

REMARKS

Claims 1-36 are presently pending in the case. The claims have not been amended. Claims 10, 23, and 33 are withdrawn from consideration but should be considered in that they depend from an allowable base claim, as discussed below.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Claim rejections under 35 USC 102

The Examiner rejected claims 1-9, 11, 15-22, 24, 25, and 28-32 under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,404,871 to Goodman et al. (hereinafter Goodman et al). The rejection is traversed.

Goodman et al et al does not anticipate claim 1, for example. To sustain a section 102 rejection, the reference relied upon, must disclose each and every element of the claimed invention. Non-disclosure of a single element of the claim negates anticipation. Claim 1 is to an aerosol drug delivery system comprising, inter alia, a disposable container adapted to contain a drug formulation and an aerosol generator for aerosolizing the drug formulation in response to manual actuation. In contrast, Goodman et al describes an automatic, electronically controlled system of actuation. As discussed in column 6 lines 47 onward, the Goodman et al system detects the patient's inspiratory flow rate and releases one or more pulses of aerosol at an identified point in the detected flow. The aerosol delivery system is discussed in column 19 beginning on line 50 as operating under the control of control circuits by selective control of a solenoid valve. Thus, in contrast to present claim 1, Goodman et al does not disclose an aerosol generator for aerosolizing the drug formulation in response to manual actuation. In Goodman et al the container is locked in an actuated position (column 19 lines 25-38) and the aerosol is electronically actuated. Since Goodman et al does not disclose all positively recited features, a section 102 rejection is precluded. Thus, the Examiner is respectfully requested to reconsider the language of claim 1 and withdraw the rejection thereunder.

Claim 17 is also not anticipated by Goodman et al. Claim 17 is to a method of aerosolizing a drug formulation comprising, inter alia, providing a container having an amount of

a drug formulation that is aerosolized in response to manual actuation. Goodman et al does not disclose a container containing a drug formulation that is aerosolized in response to manual actuation, as discussed above. Thus, Goodman et al does not anticipate claim 17.

Furthermore, claim 28 is not anticipated by Goodman et al. Claim 28 is to an aerosol drug delivery system comprising, inter alia, a control system that controls the opening of a valve such that the valve is only opened when a force is manually applied to depress the canister into the housing and when a dosing condition has been satisfied at which time a locking mechanism is in an active state. Goodman et al does not disclose this feature and does not anticipate the claim.

Claims 2-16 depend from claim 1; claims 18-27 depend from claim 17; and claims 29-33 depend from claim 28. Each of these dependent claims are not anticipated by Goodman et al for at least the same reasons as the claim from which they depend.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 12-14, 26, 27, and 34-36 under 35 USC 103(a) as being unpatentable over Goodman et al in view of PCT Publication WO 94/16759 to Ritson et al (hereinafter Ritson et al) or U.S. Patent 6,024,097 to Von Wielligh (hereinafter Von Wielligh). The rejections are traversed.

Neither Ritson et al or Von Wielligh disclose the features that Goodman et al is lacking. Accordingly, the combination of references do not render the claims unpatentable.

Conclusion

The Examiner is respectfully requested to consider and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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